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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,025	04/25/2007	Erick Carreira	0115-061069	7045

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EXAMINER	
HENRY, MICHAEL C	
ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
07/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,025	CARREIRA ET AL.	
	Examiner	Art Unit	
	MICHAEL C. HENRY	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,8,13-16 and 18-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7,8,13-16 and 18-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 04/03/08.

The amendment filed 04/03/08 affects the application, 10/575,025 as follows:

1. Claims 1, 7 and 8 have been amended. Claims 2-6, 9-12 have been canceled. New 18-28 have been added. Applicant's amendments have overcome the rejections made under 35 U.S.C. 112, second paragraph and under 35 U.S.C. 102. Consequently, the said rejections are withdrawn. However, a new ground(s) rejection is set forth herein.
2. The responsive to applicants' arguments is contained herein below

Claims 1, 7, 8, 13-16, 18-28 are pending in application

Claim Objections

Claims 18-28 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 18 is drawn to a compound according to claim 1 having the formula IIIa or formula IIId. However, the compound represented by formula IIId is not a compound according to formula I. In particular, for the compound of formula IIId, $(X)_n$ does not represent -OOC-, -COO-, -CONH- or -CH=N- as required by claim 1. On the contrary, for the compound of formula IIId, $(X)_n$ is represented by $-NH-CH_2-$ which is not included in claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-16, 26-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of artheriosclerosis or for the reduction of cholesterol levels comprising administering to a subject in need of such treatment an effective amount of a given compound, does not reasonably provide enablement for preventing said artheriosclerosis in a subject. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to a method for the treatment or prevention of artheriosclerosis or for the reduction of cholesterol levels comprising administering to a subject in need of such treatment an effective amount of a given compound.

The relative skill of those in the art: The relative skill of those in the art is high. The examiner notes that the knowledge and level of skill in this art would not permit one skilled in this art to assert a preventive therapeutic mode of administration and the skilled artisan could not immediately envisage the invention claimed.

The breadth of the claims: The instant claims are deemed very broad since these claims reads on the prevention of artheriosclerosis or the reduction of cholesterol levels comprising administering to a subject in need of such treatment an effective amount of a given compound.

Regarding the *Wands* factor (4) the predictability or unpredictability of the art:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that the recitation encompasses the preventing of artheriosclerosis in any subject comprising administering to any subject in need of such treatment an effective amount of a given compound, which is not known to have a single recognized cause. Applicant claims method for the prevention of artheriosclerosis in a subject, is not generally known to exist in this art; additionally, the disclosure is silent with regard to that which makes up and identifies the claimed method for preventing the said artheriosclerosis, which is seen to be lacking a clear description via art recognized procedural and methodological steps. In addition, the prevention of such disease or condition does not have a single recognized cause. In fact, the aforementioned disease, is recognized as having many contributing factors,

ranging from hereditary considerations, to lifestyles choices such as the diet and maintenance of bodily healthiness which includes (1) high blood pressure (2) high cholesterol (3) family history of heart disease or stroke (4) obesity (5) diabetes (6) sedentary life and lack of physical activity (7) smoking (8) viruses in the environment. These are only a few of the factors that promote these diseases in people. Applicant has not provided a description as how any cause (like the aforementioned) can be prevented, much less a description of how the said disease can be prevented. Furthermore, Applicant has not provided any clear description via art recognized procedural and methodological steps. Moreover, Applicant has not provided an adequate representation of the mode of treatment of said disease to provide a full, clear and precise indication that applicant is in possession of the members of the methodological and procedural steps which would enable the skilled artisan to practice this invention by preventing said disease. Similarly, claims 14, 15, and 26-28 which are drawn to a pharmaceutical composition for preventing arteriosclerosis are also rejected since said composition cannot prevent said arteriosclerosis, as set forth above.

Thus, the skilled artisan would view that the prevention of arteriosclerosis (which is characterized as having many contributing factors and causes) in a patient by administering to said patient the specific compound herein, as being highly *unpredictable*.

In regard to these *Wands* factors, (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary:

Moreover, it is noted that the specification provides no working examples to the prevention of said arteriosclerosis.

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the prevention of adverse effects in a patient in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of preventing arteriosclerosis in any subject as recited in the instant claims suitable to practice the claimed invention. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict the efficacy of the claimed method with a reasonable expectation of success. Therefore, the prevention of the arteriosclerosis in a patient by the said method is not enabled by the instant disclosure.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors, and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in *undue experimentation*, with no assurance of success.

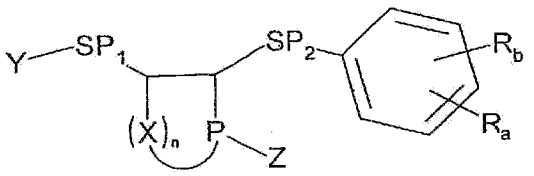
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, 8, 13-15, 18-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Dugar et al. Bioorganic & Medicinal Chemistry Letters (1995), 5(24), 2947-52 (Abstract Only).

In claim 1, applicant claims a compound according to formula I

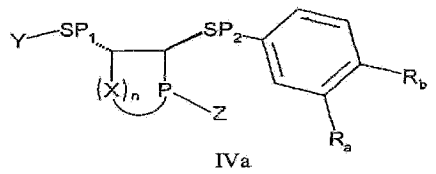


I

wherein P represents $-N<$, $(X)_n$ is -OOC-, -COO-, -CONH-, -CH=N- .....

Dugar et al. disclose applicant's compound of formula I wherein P represents $-N<$, $(X)_n$ represents -OOC-, R_a = $-OR_3$ and R_b = H or vice versa, wherein R_3 = lower alkyl (methyl), Z represents an aryl (a phenyl), Sp_1 represents $-(CH_2)_p-$ wherein p = 3, Sp_2 represents a covalent bond and Y represents an aryl (a phenyl) (see abstract). Dungar et al.'s compound has a Cas# = 173927-64-5 (see abstract).

Claim 7 is drawn to a compound according to claim 1, having the formula IVa



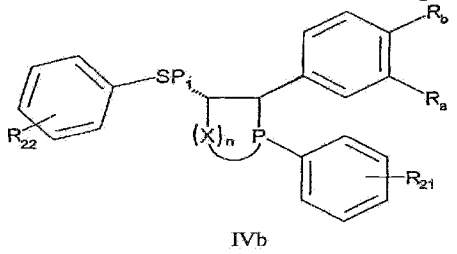
IVa

wherein P is -N=, and $(X)_n$ is -OOC-, -COO-, -CONH-, -CH=N- and R_a, R_b, Sp_1, Sp_2, Y, Z and n are as defined in claim 1.

Dugar et al. disclose applicant's compound of formula I having the formula IVa wherein P is -N=, $(X)_n$ represents –-OOC-, R_a = H, R_b = OR_3 wherein R_3 = lower alkyl (methyl), Z represents an aryl (a phenyl), Sp_1 represents $-(CH_2)_p-$ wherein p = 3, Sp_2 represents a covalent

bond and Y represents an aryl (a phenyl) (see abstract). Dungar et al.'s compound has a Cas# = 173927-64-5 (see abstract).

Claim 8 is drawn to compound according to claim 1 having the formula IVb,

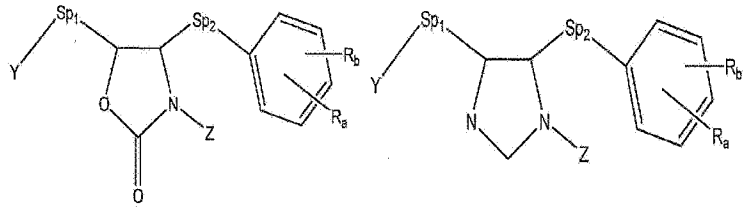


IVb

wherein P is -N=, and $(X)_n$ is -OOC-, -COO-, -CONH-, -CH=N- and R_a, R_b, Sp_1 are as defined hereinabove and wherein R_{21} and R_{22} represent H, lower alkyl, lower alkoxy or halogen.

Dungar et al. disclose applicant compound of formula IVb wherein P is -N=, $(X)_n$ represents –-OOC-, R_a = H, R_b = OR_3 wherein R_3 = lower alkyl (methyl), Z represents an aryl (a phenyl), Sp_1 represents $–(CH_2)_p$- wherein p = 3, Sp_2 represents a covalent bond and Y represents an aryl (a phenyl) and wherein R_{21} and R_{22} represent H (see abstract). Dungar et al.'s compound has a Cas# = 173927-64-5 (see abstract). Claims 13-15 which are drawn to a pharmaceutical composition of said compound with a pharmaceutically acceptable carrier, with specific intended use and a kit comprising said composition, are also anticipated by Dungar et al. since it is well settled that "intended use" of a composition or product, e.g., for treatment of artheriosclerosis or for reduction of cholesterol levels, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Furthermore, it should be noted that the said kit does not add to the patentability of the said composition, product or compound.

Claim 18 is drawn to a compound according to claim 1 having the formula IIIa or formula IIId



IIIa IIId

.....

Dungar et al. disclose applicant compound of formula IIIa wherein P is -N=, $(X)_n$ represents –-OOC-, R_a = $-OR_3$ and R_b = H or vice versa wherein R_3 = lower alkyl (methyl), Z represents an aryl (a phenyl), Sp_1 represents $-(CH_2)_p-$ wherein p = 3, Sp_2 represents a covalent bond and Y represents an aryl (a phenyl) (see abstract). Dungar et al.'s compound has a Cas# = 173927-64-5 (see abstract). Claims 19-24 which are drawn to the compound of claim 18, are also anticipated by Dungar et al. since dungar et al. disclose applicant's compound of formula IIIa wherein P is -N=, $(X)_n$ represents –-OOC-, R_a = $-OR_3$ and R_b = H or vice versa wherein R_3 = lower alkyl (methyl), Z represents an aryl (a phenyl), Sp_1 represents $-(CH_2)_p-$ wherein p = 3, Sp_2 represents a covalent bond and Y represents an aryl (a phenyl) (see abstract). Also, dependent claims 25-27 which are drawn to a pharmaceutical composition of said compound (including the compound of formula IIIa), with a pharmaceutically acceptable carrier, with specific intended use and a kit comprising said composition, are also anticipated by Dungar et al. since it is well settled that "intended use" of a composition or product, e.g., for treatment of artheriosclerosis or for reduction of cholesterol levels, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Furthermore, it should be noted that the said kit does not add to the patentability of the said composition, product or compound.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dugar et al. Bioorganic & Medicinal Chemistry Letters (1995), 5(24), 2947-52 (Abstract Only).

Claim 16 is drawn to a method for the treatment or prevention of artheriosclerosis or for the reduction of cholesterol levels comprising administering to a subject in need of such treatment an effective amount of a compound according to claim 1. Claim 28 is drawn to a method for the treatment or prevention of artheriosclerosis or for the reduction of cholesterol levels comprising administering to a subject in need of such treatment an effective amount of a compound according to claim 18.

Dugar et al. disclose applicant's compound of formula I wherein P represents  , $(X)_n$ represents -OOC-, R_a = $-OR_3$ and R_b = H or vice versa, wherein R_3 = lower alkyl (methyl), Z represents an aryl (a phenyl), Sp_1 represents $-(CH_2)_p-$ wherein p = 3, Sp_2 represents a covalent bond and Y represents an aryl (a phenyl) (see abstract). Dungar et al.'s compound has a Cas# = 173927-64-5 (see abstract). Furthermore, Dungar et al. disclose that said compound is a cholesterol absorption inhibitor (i.e., it inhibits the absorption of cholesterol) (see abstract). This

suggests that said compound can be used to inhibit the absorption of cholesterol or reduction of cholesterol levels in a subject.

The difference between applicants claimed method and the method suggested by Dungar et al. is that Dungar et al. do not exemplify the said method, per se. However, suggests that said compound can be used to inhibit the absorption of cholesterol or reduction of cholesterol levels in a subject.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to use the method suggested Dungar et al.'s to treat or reduce cholesterol levels in a subject comprising administering to said subject Dungar et al.'s compound.

One having ordinary skill in the art would have been motivated, to use the method suggested Dungar et al.'s to treat or reduce cholesterol levels in a subject comprising administering to said subject Dungar et al.'s compound, because a skilled artisan would reasonably be expected to treat or reduce cholesterol levels in a subject as suggested by Dungar et al.

Response to Arguments

Applicant's arguments with respect to claims 1, 7, 8, 13-16, 18-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be

reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

July 14, 2008.

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623